

IN THE FIGURES

Applicants note the requirement for formal drawings upon allowance of the application, as set forth in paragraph 3 of the Office Action.

REMARKS

Of the claims under consideration (claims 1-7 and 23-27), claims 1, 3-7, 23, and 25-27 stand rejected under § 103(a) in view of Willis '631 and Mikhail '934, as set forth in paragraph 4 of the Office Action. Claims 2 and 24 stand rejected under § 103(a) as unpatentable over Willis '631, and further in view of U.S. Patent Publication No. '501 to Osbourne or the '734 patent to Copenhaver, as set forth in paragraph 5 of the Office Action.

With respect to the status of U.S. Patent No. 6,264,631 to Willis et al. as a prior art reference, the Examiner is respectfully informed that the assignee of the '631 patent (Ballard Medical Products) and the assignee of the present application (Kimberly-Clark Worldwide, Inc.) are commonly owned by Kimberly-Clark Corporation of Neenah, Wisconsin. Thus, the '631 patent is not a proper § 102(e) reference for use in a § 103 combination against the present application. However, U.S. Patent No. 5,997,503 issued from a parent application to the Willis '631 patent, contains the identical disclosure as Willis '631, and is a proper prior art reference. Thus, for purposes of this Amendment, Willis '631 will be treated as Willis '503.

Applicants also wish to point out to the Examiner that commercial products containing duckbill valves made in accordance with Willis '503 are also proper prior art devices to the present application.

The § 103 obviousness rejection is premised on the proposition that Mikhail '934 provides the suggestion and motivation to modify the duckbill type of valve described in Willis '503 in accordance with the presently claimed invention. Applicants respectfully submit that such a combination cannot be properly made.

When used in a § 103 obviousness rejection, a prior art reference must be considered in its entirety for all that it teaches. It is improper to simply pick and choose isolated selected passages or statements from a reference for purposes of making an obviousness rejection without considering the reference in its entirety. In this case, the Mikhail '934 reference expressly teaches against the use of the type of duckbill valves that are the subject matter of Willis '503 and the present invention. A significant portion of the "Background" section of the '934 patent addresses alleged deficiencies with duckbill valves. (see Col. 3, line 17 to Col. 4 to line 20)

A purpose of the invention of Mikhail '934 was to offer a valve substantially different from a duckbill valve. Under the "Summary" section of the patent at column 5, lines 31 through 36, the patent states the following as an object of the invention:

It is an additional object of this invention to fabricate the above multi-axial valve using a method that enhances or enlarges the valves seating or contact area compared with conventional duckbill or dome-type valves, and ensures that the valve elements consistently and reliably return to the proper closed configuration.

The entire disclosure of the '934 patent deals with a palpitatable valve that includes a multi-axial dome-type construction with a peripheral trough surrounding the dome adjacent to and displaced from a wall of the valve body. This configuration is fundamentally different from a duckbill valve. Applicants respectfully submit that those of ordinary skill in the art would not glean from the '934 patent any teaching to improve

a duckbill valve by modifying the durometer of the valve material or thickness of the valve walls. At most, one skilled in the art would look to the '934 reference as a teaching to not use a duckbill valve.

The multi-axial dome membrane 38 described as an internal component of the valve 36 of Mikhail '934 has a substantially different structure and configuration as compared to a duckbill valve. There is no teaching or suggestion of any sort in the reference that would lead one skilled in the art to modify the durometer value of the flexible walls of the duckbill valve. As stated in the present application, conventional duckbill valves have generally been made of a silicon rubber having a durometer rating of about 50 Shore. This essentially corresponds to the preferred value of about 40 Shore disclosed in the '934 patent. One skilled in the art would certainly not see this as a teaching of any sort to decrease the durometer value of a flexible wall in a duckbill valve to below about 20 Shore.

In addition, the durometer references set forth in column 9 of the '934 patent do not teach that any benefit may be found from forming the valve member of a duckbill valve with a material having a durometer of less than about 20 Shore. In fact, the reference confirms the conventional valve of about 50 for duckbill valves. For example, although the reference states that the durometer value for the flexible membrane 38 within the valve 36 may have a durometer value of about 12 to about 95, the reference expressly teaches that a more preferable durometer value is about 25 to about 60, and an even more preferable range is about 35 to 45, and the most preferred embodiment is about 40 Shore. Thus, one skilled in the art reading this reference in its entirety would not be motivated to reduce the Shore value of the valve material in a duckbill valve to

under 20 when this reference expressly teaches that it is more preferred for the Shore value of the membrane to be substantially higher than 20, most preferably about 40 Shore. The initial indicated range of 12 to about 95 Shore cannot be read in isolation. One must consider that the reference teaches that the preferred value and ranges are substantially higher than 20 Shore. One skilled in the art would be motivated towards these higher values. One would not be motivated to values less than 20 unless there was a teaching or expectation that such lower values would provide a greater benefit compared to the most preferred value of 40. Such expectation or motivation does not exist. As set forth on page 9 of the specification, against the teaching of the art and conventional devices, "applicants have discovered that use of a substantially lower durometer material than had been previously used in the art for the valve member unexpectedly provides an improved seal and greater seal flexibility without sacrificing the structural integrity of the valve member."

Accordingly, for at least the reasons set forth above, applicants respectfully submit that independent claims 1, 6, 23, and 26 are allowable over the cited combination.

In addition, independent claims 23 and 26 further call for at least one of the flexible opposing walls to have a first portion with a durometer of about 50 Shore and a second portion having a durometer of less than about 20 Shore, the second portion being disposed at the respective end of the wall and the first portion being disposed spaced from the respective end. There is no suggestion or motivation of any sort in Mikhail '934 to modify the flexible walls of a duckbill valve to have varying durometer values as set forth in claims 23 and 26. Applicants respectfully submit that independent


claims 23 and 26 are independently allowable over the cited combination for at least this reason.

With this Amendment, applicants respectfully submit that the claims under consideration (claims 1-7 and 23-27) are allowable over the applied combination of references. Favorable action thereon is respectfully requested.

The Examiner is encouraged to contact the undersigned at his convenience should he have any questions regarding this matter or require any additional information.

Respectfully submitted,

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